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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,978	11/24/2003	Gregg Budahazi	1530.0550001/JUK/JCI	1745

26111 7590 07/09/2007

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,978	BUDAHAZI ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed April 16, 2007. Claims 1-34 were previously pending, with claims 1-20 withdrawn from consideration. Applicants amended claims 21-27, 30 and 31, and added new claims 35-39. Claims 1-39 are pending. Claims 21-39 will be examined.

2. Applicants' amendments overcame the following rejections: rejection of claims 22-26 and 30-34 under 35 U.S.C 112, second paragraph; rejection of claims 22 and 23 under 35 U.S.C 102(b) as anticipated by Nochumson et al. All other previously presented rejections are maintained for reasons given in the "Response to Arguments" below.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on February 6, 2007 was filed after the mailing date of the non-final office action on October 16, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

4. Applicant's arguments filed April 16, 2007 have been fully considered but they are not persuasive.

Regarding the rejection of claims 21-39 under 35 U.S.C. 102(b) as anticipated by Nochumson et al., Applicants argue that the newly amended claims are not anticipated by Nochumson et al. However, as can be seen in the rejection presented below, Nochumson et al. anticipates claims 21 and 24-39.

The rejection of claims 21 and 24-34 are maintained, and the rejections of claims 35-39 are added.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-39 are indefinite in claim 30. Claim 30 is indefinite over the recitation of "wherein said DNA product contains an amount of host cell derived impurities that is undetectable by any one of a group consisting of: LAL assay, Southern blot assay, chromatography, Northern blot assay, and ethidium bromide agarose analysis."

It is not clear what are the meets and bounds of this claim. As the detection limit of any particular assay depends on the conditions under which it is performed as well as the ingredients used, the level of impurities detected will depend on where and how the assay is performed. Applicants did not specify conditions and cutoff values for any of these assays which would result in undetectable levels of impurities.

Claim Interpretation

7. Applicants did not define the term "about X units", therefore any reasonable value below or above a given number X is considered to anticipate this term.

8. In view of the indefiniteness of claims 30-39, any level of impurities is considered as anticipatory of these claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21 and 24-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Nochumson et al. (US 2001/0034435 A1; cited in the IDS and in the previous office action).

Regarding claims 21 and 28-39, Nochumson et al. teach plasmid DNA and pharmaceutical preparation (page 8, [0099]). Nochumson et al. teach plasmid DNA preparation with 95% plasmid DNA and less than 5% RNA, anticipating the range from about 0.00001% to about 5% RNA (page 8, [0099]) and undetectable amount of RNA product. Nochumson et al. teach plasmid DNA preparation with 0.05% of host DNA (page 8, [0099]), which is equivalent to 0.0005 μg of host DNA/μg of DNA product, therefore Nochumson et al. anticipate the range from about 0.00004 to 0.002 μg of host DNA/μg of DNA product and undetectable amount of the host genomic DNA. Nochumson et al. teach plasmid DNA preparation with less than 0.06% of protein (page 8, [0099]), which is equivalent to 0.0006 μg of protein/μg of DNA product, therefore Nochumson et al. anticipate the range from about 0.00000001 to about 0.001 μg of protein/μg of DNA product and undetectable amount of protein. Nochumson et al. teach plasmid DNA preparation with less than 0.2EU/mg of endotoxin, which equals less than 0.0002 EU/μg (page 8, [0099]), anticipating the range from about 0.00001 to about 0.01 EU/μg and undetectable amount of endotoxins (=pyrogens). They teach pharmaceutical preparations (claims 8, 11, 19, 31).

Regarding claims 24 and 27, Nochumson et al. teach plasmid DNA preparation with 0.05% of host DNA (page 8, [0099]), which is equivalent to 0.0005 μg of host DNA/μg of DNA product, therefore Nochumson et al. anticipate the limitations of about 0.00004 and of 0.0005 μg of host DNA/μg of DNA product.

Regarding claims 25 and 26, Nochumson et al. teach plasmid DNA preparation with less than 0.2EU/mg of endotoxin, which equals less than 0.0002 EU/μg (page 8, [0099]), anticipating the values of about 0.0002 and about 0.0001 EU/μg of DNA product.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nochumson et al. (US 2001/0034435 A1; cited in the IDS and in the previous office action).

Regarding claims 22 and 23, Nochumson et al. teach plasmid DNA preparation with less than 5% RNA (page 8, [0099]), but do not teach preparations with about 0.00001% to 0.0001% RNA or preparations with 0.0001% RNA.

However, it would further have been prima facie obvious to perform routine optimization to arrive at the desired levels of RNA impurities, as noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of the specific impurities concentrations was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

13. No claims are allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
7/31/07